UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL NO. 1456** **CIVIL ACTION: 01-CV-12257-PBS** **Judge Patti B. Saris**
THIS DOCUMENT RELATES TO ALL ACTIONS	

ABBOTT LABORATORIES' MEMORANDUM
OF LAW IN SUPPORT OF ITS MOTION TO DISMISS

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Abbott Laboratories ("Abbott") asserts four arguments in support of dismissal not addressed in the Defendants' Consolidated Memorandum: (1) plaintiffs lack standing against Abbott; (2) the allegations against Abbott do not satisfy Rule 9(b); (3) plaintiffs' state law claims are preempted under *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001); and (4) the claims of the ERISA plan plaintiffs should be dismissed under Rule 17(a).

I. PLAINTIFFS LACK STANDING AGAINST ABBOTT

The Complaint should be dismissed for failure to allege facts sufficient to establish Article III standing against Abbott. To allege standing, plaintiffs "must allege personal injury *fairly traceable* to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Allen v. Wright,* 468 U.S. 737, 751 (1984) (emphasis added). As argued more fully in the Memorandum Of Bayer Corporation In Support Of Its Individual Motion To Dismiss (and incorporated herein), a plaintiff must allege payment for an *Abbott-manufactured* drug to have standing. Except United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW"), no plaintiff alleges payment for an Abbott-manufactured drug. For this reason alone, all plaintiffs except UFCW lack standing.

A closer examination of the Complaint reveals that UFCW also lacks standing. UFCW alleges that it "paid charges" for five "Covered Drugs" manufactured by Abbott. *See* Compl. ¶ 26. These payments of charges allegedly consisted of Medicare co-payments incurred by UFCW members and paid by UFCW. *See* Compl. ¶ 4. UFCW does not allege that these Medicare co-payments were based on the AWPs of Abbott drugs. *See id.* This distinction between charges and AWP is critical. Under 42 C.F.R. § 405.517(b), Medicare co-payments are 20% of the *lesser* of the healthcare provider's charges or 95%-of-AWP. Accordingly, under the allegations of the Complaint, UFCW's alleged overpayments are not "traceable" to Abbott, but

to the providers who set the charges that UFCW paid. As such, UFCW lacks standing.

A brief mention of plaintiff Shirley Geller's lack of standing also is warranted. Geller alleges that she overpaid for the generic drug vancomycin, which is manufactured by many companies. *See* Compl. ¶ 13. Geller does not allege that Abbott manufactured the vancomycin that was administered to her, or that the AWP of Abbott's vancomycin affected her Medicare co-payment. *See id.* While the Complaint contains allegations about the AWP of Abbott's vancomycin (*see* Compl. ¶¶ 184-97), these general allegations do not confer standing upon Geller, who has failed to allege any injury "traceable" to Abbott.

II. THE ALLEGATIONS AGAINST ABBOTT DO NOT SATISFY RULE 9(B)

A. All Plaintiffs Fail To Satisfy Rule 9(b)

Rule 9(b) applies to both the RICO and the state law consumer fraud counts because they are based on "averments of fraud."[1] A Complaint that fails to provide the "who, what, when, where and how" of the alleged fraud should be dismissed under Rule 9(b). *See Suna v. Bailey Corp.*,107 F.3d 64, 68 (1st Cir. 1997). In this case, plaintiffs do not plead with particularity core facts of the alleged fraud, such as: (i) what Abbott said to Medicare, to industry publications, or to plaintiffs concerning the AWPs for drugs; (ii) when those statements were made; (iii) who made the statements; (iv) to whom they were made; (v) who relied upon the statements; and (vi) how they relied upon them. These fundamental failings are fatal under Rule 9(b).

Rule 9(b) also requires that a plaintiff plead with particularity the consequences of the alleged fraud: that is, how the plaintiff was injured by the conduct. *See Schwartz v. Celestial Seasonings, Inc.*, 124 F.3d 1246, 1252 (10th Cir. 1997) (requiring plaintiff to specify "the

[1] *See Doyle v. Hasbro, Inc.*, 103 F.3d 186,194 (1st Cir. 1996) (Rule 9(b) "applies to RICO cases"); *Varney v. R.J. Reynolds Tobacco Co.*, 118 F. Supp. 2d 63, 72 (D. Mass. 2000) (dismissing consumer fraud act claim for failure to comply with Rule 9(b)).

consequences" of the alleged fraud); *Rolo v. City Inv. Co. Liquidating Trust*, 155 F.3d 644, 659 (3d Cir. 1998) (same). As noted above, plaintiffs fail to allege that they were injured at all by Abbott, let alone satisfy Rule 9(b) by describing how they were injured.

Additionally, the plaintiffs do not explain how or why it is fraudulent for an AWP to exceed actual acquisition cost. The federal government and the media understood and repeatedly described AWP as a "sticker price" that substantially exceeds the price at which drugs are sold. *See* Cons. Mem. at 3-20. Plaintiffs do not allege how it is fraudulent for an AWP to exceed acquisition cost when Congress, the President and HCFA repeatedly called AWP a "sticker price" that is not related to sales price. Significantly, plaintiffs do not allege that any Defendants ever represented that the AWPs for their drugs were anything other than "sticker prices." These omissions are fatal, as Rule 9(b) requires a plaintiff to specify why an alleged fraudulent statement is false. *See Suna,* 107 F.3d at 68 (requiring plaintiff to explain why statements were fraudulent); *Mills v. Polar Molecular Corp.,* 12 F.3d 1170, 1175 (2d Cir. 1993) (same).

The facts of this case closely resemble *United States ex rel. Gublo v. NovaCare, Inc.,* 62 F. Supp. 2d 347 (D. Mass. 1999), in which Judge Stearns dismissed a Medicare fraud case under Rule 9(b) because the plaintiff failed to allege why or how the defendant's price representations were fraudulent. The defendant in *Gublo* was a supplier of medical devices accused of defrauding Medicare by submitting reimbursement claims that set forth charges for devices that did not reflect the discounts routinely given to non-governmental payors and purchasers. *See id.* at 354-55. Dismissing the Complaint under Rule 9(b), the court noted that the plaintiff "fail[ed] to point to any section of the [Medicare] regulations that requires [defendant] to factor discounts given to private insurers into the determination of its 'actual charges' for government billing purposes." *Id.* Here also, plaintiffs allege that Medicare and others overpaid for drugs because

defendants allegedly reported AWPs that substantially exceed sales price in the non-Medicare market. As in *Gublo*, plaintiffs cannot identify any Medicare statute or regulations that requires AWPs to be based on actual sales prices. To the contrary, Congress purposefully selected AWP as the Medicare reimbursement benchmark, knowing that it frequently exceeded acquisition cost. These contradictory allegations do not satisfy Rule 9(b).

B. UFCW Fails To Plead Fraud With Particularity

UFCW's bare allegation that it paid for five Abbott-manufactured drugs also does not satisfy Rule 9(b). *See* Compl. ¶ 26. Those allegations do not account for how Medicare pays for multiple-source or "generic" drugs, such as the five attributed by UFCW to Abbott. Under 42 C.F.R. § 405.517(c), no single manufacturer's AWP determines Medicare payment for a generic drug. Rather, Medicare pays based on the lesser of: (i) the provider's charge; (ii) 95% of the median AWP for all generic forms of the drug; or (iii) 95% of the lowest AWP of the brand name form of the drug. As a matter of law, Abbott cannot determine the Medicare reimbursement for the drugs identified by UFCW. Given this regulatory scheme, UFCW must explain how Abbott's allegedly inflated AWPs resulted in injury to UFCW or face dismissal pursuant to Rule 9(b).

In addition, this regulatory framework renders nonsensical plaintiffs' allegations about "marketing the spread." *See* Compl. ¶ 172. Pursuant to law, the Medicare allowable for all forms of a generic drug is the same. *See* 42 C.F.R. § 405.517(c). One company cannot, therefore, "market the spread" by "manipulating" its AWP to gain competitive advantage over another company. Accordingly, the Complaint's allegations of fraud in connection with Abbott's generic drugs do not satisfy Rule 9(b), and the Complaint should be dismissed.

C. Plaintiff Geller Fails To Allege When She Took Vancomycin

Geller does not allege that the vancomycin she received was manufactured by Abbott. Geller also does not allege the date when the vancomycin was administered or when she made her Medicare co-payment. These failures are fatal under Rule 9(b). *See Learning Express, Inc. v. Ray-Matt Enters.*, 74 F. Supp. 2d 79, 86 (D. Mass. 1999). That is doubly true in this case, because Medicare ceased covering vancomycin on September 1, 1996. *See* 61 Fed. Reg. 66676, 66684 (Dec. 18, 1996). Geller could not, therefore, have made a Medicare co-payment for vancomycin within the applicable four-year statutes of limitations. *See Agency Corp. v. Malley-Duff & Assocs., Inc.* , 483 U.S. 143, 155 (1987) (RICO); *Karl Storz Endoscopy-Am., Inc. v. Surgical Techs., Inc.*, 285 F.3d 848, 855 (9th Cir. 2002) (Cal. Bus. and Prof. Code § 17200 *et seq.*). Geller's claims should, therefore, be dismissed.

III. PLAINTIFFS' STATE LAW CLAIMS ARE PREEMPTED UNDER *BUCKMAN*

As argued in Defendants' Consolidated Memorandum, Plaintiffs' state law claims should be dismissed because they are preempted by federal law governing the Medicare program. *See* Cons. Mem. at § IV. Those state law claims should be dismissed for the additional reason that they conflict with the fraud enforcement provisions of the Medicare Act and other federal laws addressing fraud in the Medicare Program. The Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), is precisely on point.

In *Buckman*, the plaintiffs claimed that the manufacturer of orthopedic screws deceived the FDA about the screws' intended use in order to obtain FDA marketing approval. The plaintiffs alleged that but for the misrepresentations, the FDA would not have granted marketing approval, the screws would not have been marketed, and they would not have been injured. The Supreme Court unanimously held that the plaintiffs' fraud-on-the-agency claims conflicted with

the FDA's ability to "make a measured response to suspected fraud" committed against it, and to "police fraud consistently with [the agency's] judgment and objectives." *Id.* at 349, 350. Consequently, the Court held that the plaintiffs' state law claims were preempted. S*ee id; see also Nathan Kimmel, Inc. v. Dowelanco*, 275 F.3d 1199, 1208 (9th Cir. 2002) (state law claims premised on a fraud-against-EPA theory preempted under *Buckman)*; *Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 721 (E.D. Tenn. 2001) (state law claims premised on a fraud-against-OSHA theory preempted under *Buckman).*

This matter presents a stronger case for preemption. As in *Buckman*, the Secretary of HHS is charged with policing fraud on his agency. In fact, the Secretary has discretionary fraud-fighting powers at least equal to the FDA's powers described in *Buckman*. For example, the Secretary of HHS has independent authority to investigate fraud through the Office of Inspector General and to impose civil monetary penalties in administrative proceedings before resorting to the courts. *See* 42 U.S.C. § 1320a-7a(a)(1) & (7); 42 C.F.R. § 1003.102; 31 U.S.C. § 3801; 45 C.F.R. §§ 79.1 *et seq*. The Secretary likewise has administrative power to exclude persons and entities from participating in Medicare and, by regulation, has extended that sanction to pharmaceutical manufacturers. *See* 42 U.S.C. § 1320a-7; 42 C.F.R. §§ 1001.901 & 1001.951(a). Physicians and other providers can see their provider agreement terminated by HHS. *See* 42 C.F.R. §§ 489.53 & 489.54(a). All of these powers are backed up by extensive subpoena and investigatory powers. *See* 42 U.S.C. § 1320a-7(12); 45 C.F.R. § 79.4; 5 U.S.C. Appx. § 6.

Because of these powers and the agency's regulatory mission, HHS has a close relationship with the pharmaceutical and medical community. As the Court noted in *Buckman*, such a "relationship between a federal agency and the entity it regulates is inherently federal in character." *Buckman*, 531 U.S. at 347. State law cannot be permitted to interfere. In this case,

as in *Buckman*, "[t]he conflict stems from the fact that the federal statutory scheme amply empowers the [agency] to punish and deter fraud against the Administration, and that this authority is used by the [agency] to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. The Court should not permit plaintiffs to use their state law claims to alter or supplement HHS's agenda for combating fraud — particularly in this case where the alleged "fraud" consists of price reporting practices about which HHS and Congress were well aware.

Plaintiffs' state law claims, if permitted to go forward, would impermissibly increase the burdens facing Medicare suppliers, HCFA and the carriers. As the Court noted in *Buckman*, complying with a federal "regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing" regulated entities. *Id.* at 350. If the state claims here are permitted to go forward, Medicare suppliers will be forced to contend with fifty states' varying laws, as well as federal Medicare rules, whenever they speak to or interact with the federal government regarding the Medicare program. In a federal program such as Medicare, this burden would be too great. As in *Buckman*, the threat of state fraud claims would cause Medicare suppliers to fear that their interaction with the agency "will later be judged insufficient in state court." *Id.* at 351. In *Buckman*, the Supreme Court stated that the FDA's ability to carry out its duties would be hindered if it had to contend with device manufacturers who tailored their submissions to comply with 50 states' tort laws as well as the FDA's rules *See id.* So also here, HCFA and the carriers could not as effectively carry out their statutory duties were healthcare providers and drug manufacturers required to comply with 50 states' tort laws in addition to federal law governing Medicare reimbursement and price reporting.

As a result, plaintiffs' state law claims are preempted and should be dismissed.

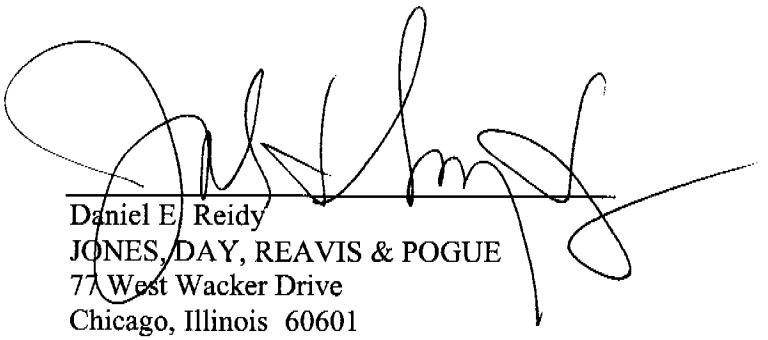
IV. THE ACTIONS BROUGHT BY THE ERISA PLAN PLAINTIFFS SHOULD BE DISMISSED UNDER RULE 17(a)

Plaintiffs CMHV, THWF, TCBW and UFCW are employee benefits plans under ERISA. *See* Compl. ¶¶ 23-26. As such, they are trusts. *See Lenon v. St. Paul Mercury Ins. Co.,* 136 F.3d 1365, 1370 (10th Cir. 1998). Under Fed. R. Civ. P. 17(a), the trustees of CMHV, THWF, TCBW and UFCW are the real parties in interest with authority to bring suit, not the trusts themselves. These trusts cite 29 U.S.C. § 1132(d) as alleged authority permitting them to bring action in their own names. *See* Compl. ¶¶ 23-26. That statute creates an exception to Rule 17(a) to permit ERISA plans to bring certain actions in their own names "under this title," *i.e.,* under ERISA. The statute does not, however, abridge Rule 17(a) for the non-ERISA claims at issue here. *See* 29 U.S.C. § 1132(d). As a result, the claims of CMHV, THWF, TCBW and UFCW should be dismissed unless the Complaint is corrected within a "reasonable time" to substitute the trustees of CMHV, THWF, TCBW and UFCW as plaintiffs. *See Yale Fin. Serv. Trust v. Palmetto Packers, Inc.*, 1987 WL 20140, *1 (N.D. Ill. Nov. 19, 1987).

CONCLUSION

For the foregoing reasons, as well as those stated in the Consolidated Memorandum, the Court should dismiss the Master Consolidated Amended Class Action Complaint as to Abbott.

Dated: November 4, 2002



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